

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN, INC.,

Plaintiff,

v.

DEVA HOLDING A.S.,

Defendant.

Civil Action No. 2:16-cv-1447 (WCB)

**DEVA’S RENEWED UNOPPOSED MOTION REQUESTING
TERMINATION OF THE 30-MONTH STAY OF FDA APPROVAL
AND MEMORADUM OF LAW IN SUPPORT THEREOF**

At the Court’s invitation (Dkt. 51), Defendant DEVA Holding, A.S. (“Deva”) hereby submits this Renewed Unopposed Motion and Memorandum of Law in support, requesting that this Court requesting that the FDA terminate the thirty-month regulatory stay of approval of Deva’s ANDA.

The parties previously jointly moved for an order of this Court (1) staying this case (“the Deva case”) pending the outcome of the related appeal to the United States Court of Appeals for the Federal Circuit in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:15-cv-1455-WCB (E.D. Tex.), Case No. 2018-1130 (Fed. Cir.) (“the lead case”); (2) binding the parties on the outcome of that related appeal in the lead case; and (3) terminating the 30-month stay of the FDA’s approval of Deva’s ANDA in the Deva case. (Dkt. 50). The Court subsequently ordered: (1) that the present case is stayed until such time as the Federal Circuit in the lead case appeal, Case No. 2018-1130, issues its mandate or otherwise terminates the appeal; (2) that the Parties will be bound by the results of the appeal in the lead case, Case No. 2018-1130, and any

proceedings on remand, as necessary; and (3) that Plaintiff Allergan, Inc. (“Allergan”) retains its right to later file a motion seeking to join the Saint Regis Mohawk Tribe (“the Tribe”) as a co-plaintiff in the Deva case, and Deva retains its right to oppose such a joinder. (Dkt. 51). The Court declined to grant the Parties’ motion requesting that FDA terminate the 30 month stay of approval of Deva’s ANDA No. 209811 pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), but invited the Parties to renew their motion and include a memorandum of law setting forth the Court’s authority.

21 U.S.C. 355(j)(5)(B)(iii) provides that where, as here, an Abbreviated New Drug Application (“ANDA”) contains a paragraph IV certification and “an action is brought before the expiration of” a 45-day period from the date a paragraph IV notice letter is received, FDA may not approve that application for a “thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action[.]” However, where a district court “decides that the patent is invalid or not infringed” before the expiration of the 30-month stay, FDA may approve the ANDA on “the date on which the court enters judgment reflecting the decision.” In the related case of *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:15-cv-1455-WCB (E.D. Tex.) (“the lead case”), this Court entered a final judgment that claims 26 and 27 of U.S. Patent No. 8,629,111 (“the ‘111 patent”); claims 1, 11, 13, 14, and 23 of U.S. Patent No. 8,648,048 (“the ‘048 patent”); claim 35 of U.S. Patent No. 8,685,930 (“the ‘930 patent”); and claims 13, 16, 22, 26, and 27 of U.S. Patent No. 9,248,191 (“the ‘191 patent”) are invalid for obviousness. (Dkt. 524). Under the clear language of the statute, this judgment of invalidity terminated the 30-month stay and authorized FDA to approve the relevant ANDAs, assuming all other requirements were met.

Deva and Allergan have agreed that the substantive (non-settlement) court outcome of the lead case appeal (Case No. 2018-1130 (Fed. Cir.)), and any substantive (non-settlement) court proceedings on remand, if necessary, will be binding on the parties in the present case and will resolve the entirety of the dispute between them on all issues, including, but not limited to, infringement and invalidity. Allergan has also agreed that it will not later assert any claims of the '111, '048, '930, or '191 patents other than those invalidated in the lead case against Deva's ANDA No. 209811. The practical effect of the foregoing is that Deva is now similarly situated with the defendants in the lead case and, should the Federal Circuit affirm or reverse, in whole or in part, this Court's finding of invalidity, that judgment (and any judgment on remand, if necessary) will be binding on Allergan and Deva in this case as if Deva were a party to the appeal. Thus, no triable issues regarding infringement or invalidity remain in the present action for this Court to decide. Therefore, the Court has the authority under 21 U.S.C. § 355(j)(5)(B)(iii) to request that the FDA terminate the 30-month regulatory stay of approval of Deva's ANDA No. 209811.

Termination of the 30-month stay in this case is consistent not only with FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iii), but also with Congressional intent "to stay generic approval until the litigation is resolved." *Apotex v. FDA*, 1:06-cv-01890, D.I. 13 at 23-24 (D.D.C., Nov. 17, 2006). In its own words, "FDA has reasonably interpreted this provision to allow the termination of 30-month stays when patent litigation is concluded without a formal court decision." *Id.* Termination of the 30-month stay is appropriate where, as in this case, the parties have elected to resolve their dispute by means of an agreement to be bound by the outcome of the appeal in the lead case, and conclude the present litigation without proceeding to a formal decision.

Further, 21 C.F.R. 314.107(b)(3)(vi), enacted as part of the FDA's recent amendments to the regulations, provides that the 30-month stay will terminate and an ANDA may be approved if the patent owner, or exclusive patent licensee, "agrees in writing that the . . . ANDA may be approved any time on or after the date of the consent." *Id.* While section 314.107(b)(3)(vi) has yet to be interpreted by the courts, in enacting this new provision, the FDA affirmed that "it expressly permits the party that receives the benefit of the statutory 30-month stay to waive that benefit." *Abbreviated New Drug Applications*, 81 Fed. Reg. 194, V.M.2.h. (Oct. 6, 2016) (codified as 21 C.F.R. 314.107(b)(3)(vi), Dec. 5, 2016). By way of the parties' joint motion (Dkt. 50) requesting "that this Court enter an Order requesting that FDA terminate the 30-month stay of FDA approval on Deva's ANDA No. 209811," Allergan provided its express written consent that the 30-month FDA stay, on its own, no longer prevented approval of Deva's ANDA. Thus, 21 C.F.R. 314.107(b)(3)(vi) also provides authority for this Court to terminate the 30-month stay..

Last, 21 C.F.R. 314.107(b)(3)(vii), also recently enacted by FDA, explicitly contemplates that a court may enter "an order requiring the 30-month . . . period to be terminated." *Id.* FDA may then approve the ANDA "in accordance with the court's order." *Id.* Again, while this new provision has not yet been interpreted by a court, the language of section 314.107(b)(3)(vii), on its face, does not limit a court's authority to order termination of the 30-month stay to any particular set of circumstances. In fact, in considering a comment recommending "that FDA revise § 314.107(b)(3)(i) to accept any reason a court provides for reducing the 30-month stay, and not solely an extension or reduction of the 30-month stay because of a failure of the applicant or patent owner to cooperate reasonably in expediting the action," FDA responded that "§ 314.107(b)(3)(vii) adequately addresses the concern described in the comment by providing

for termination of the 30-month stay if the court enters an order requiring the 30-month stay to be terminated.” Abbreviated New Drug Applications, 81 Fed. Reg. 194, V.M.2.c. (Oct. 6, 2016). Accordingly, FDA contemplates that a court may enter an order requesting that FDA terminate the 30-month stay. Thus, this Court also has authority under 21 C.F.R. 314.107(b)(3)(vii) to order termination of the 30-month stay of Deva’s ANDA.

Pursuant to the foregoing, Deva renews its request that this Court enter an Order terminating the 30-month stay of FDA approval on Deva’s ANDA No. 209811, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), 21 C.F.R. 314.107(b)(3)(vi) and/or 21 C.F.R. 314.107(b)(3)(vii).

Dated: May 30, 2018

Respectfully submitted,

/s/ Jennifer Parker Ainsworth

Jennifer Parker Ainsworth

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this motion was served on all counsel who have consented to electronic service, Local Rule CV-5(a), on this 30th day of May, 2018.

/s/ Jennifer P. Ainsworth
Jennifer P. Ainsworth